REMARKS

Status of the Claims

Claims 1-12, 14-41, 43-45, 48-61, and 74-87 are pending in the present application, Claims 42, 46, and 62-73 having been previously canceled as being directed to a non-elected invention, and Claims 13 and 47 having been currently canceled. Claims 4-6, 10-14, 17-19, and 36 are directed to a non-elected species, but will be entitled to consideration upon allowance of a generic claim. Claims 1, 2, 3, 7, 12, 14, 18, 19, 45, 48, 49, 51-57, 74 and 79 having been amended to more clearly distinguish the recited subject matter over the cited art.

Brief Summary of Telephone Interviews of July 2007

Applicant's attorney (Sabrina MacIntyre, Registration No. 56,912) held a brief telephone interview with Examiner Musselman on July 3, 2007, to discuss what applicant believed may be typographical errors on page 2 of the Office Action dated April 19, 2007. First, applicant had noted that under the section entitled "Status of Claims," it did not appear that Claim 10 was withdrawn from consideration, as had been indicated in the Office Action dated March 10, 2006. Examiner Musselman confirmed that this was a typographical error and that Claim 10 is withdrawn from further consideration by the Examiner. Second, applicant noted under the section entitled "Priority" that Claim 2 was afforded the earlier filing date of 10/23/2000 and that later in this section, Claim 2 was also afforded the filing data of 11/20/2003. Examiner Musselman confirmed that at the bottom of page 2, there is a typographical error because the last sentence should read that Claim 1, not Claim 2, is supported by the parent application and will be afforded the earlier filing date. Applicant's attorney thanks Examiner Musselman for providing this clarification.

In addition, applicant's attorneys (Sabrina MacIntyre, Registration No. 56,912 and Michael King, Registration No. 44,832) held a brief Telephone Interview with Examiner Musselman on July 18, 2007, to discuss the Restriction Requirement previously issued by a different Examiner. Applicant's attorney thanks Examiner Musselman for clarifying his position on the previously issued Restriction Requirement.

Priority under 35 U.S.C. § 120

Applicant acknowledges the Examiner's position with respect to the priority claim.

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Rejoinder of Claims withdrawn from Consideration Due to the Restriction Requirement

A species restriction was previously imposed by a different Examiner. Claims 4-6, 10-14, 17-19, and 36 were withdrawn from consideration as being directed to a non-elected species. Significantly, such claims are dependent claims; and as discussed in detail below the corresponding independent claims have been amended to patentably distinguish over the cited art. Rejoinder of such claims is thus appropriate.

Amendment to the Drawings

FIGURE 10D has been amended to correct an element number. A formal replacement drawing with this Figure is submitted that has thus been corrected.

Amendment to the Specification

The specification has been amended above to correct minor typographical errors. No changes to the subject matter have been made.

Rejections of Claims under 35 U.S.C.§ 112, Second Paragraph

The Examiner has rejected Claims 7-9 under 35 U.S.C. § 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language, and that this claim is an omnibus type claim. More specifically, the Examiner indicates that it is unclear what applicant means by "when at least a portion of the simulated physiological structure is touched" because it is unclear what manner of touching applicant is claiming (i.e. touched with a hand, medical instrument, etc.).

Accordingly, applicant has amended a portion of Claim 7 to recite "either by a user of the physiological training and evaluation simulator, or by an object used in connection with performing the simulated procedure." Support for this amendment is provided below:

> Note that touch sensitive switches (as opposed to switches that must be flipped or pushed to make and break a mechanical connection) are commonly used in many devices, such as touch screen displays and microwave oven controls. Touch sensitive switches can be configured to operate under several different principles, including temperature sensitive switches (commonly found in elevator buttons configured to respond to the warmth of the human finger), resistance sensitive switches (closely adjacent contacts, at least one of which can be deflected to close the circuit), radio sensitive switches (switches configured to sense a change in radio-wave reception that occurs when the switch is touched by an object that acts as an antenna), and capacitance sensitive switches (switches configured to determine when the switch is touched by an object that changes the inherent capacitance of the switch). While temperature sensitive switches, resistance sensitive switches, and radio sensitive

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> switches generally do not determine the magnitude of the pressure applied to the switch, if a circuit requires sensing only that the switch has been touched, any of the above types of touch sensitive switches can be incorporated into a conductive elastomer-based evaluation circuit. (Emphasis added, specification, page 40, lines 1-17.)

As highlighted by the underlined portion above, the warmth of the human finger, an object that acts as an antenna, or an object that changes the inherent capacitance of the switch (e.g., a finger or medical instruments) can all be utilized with a touch sensitive switch. Other portions of the disclosure clearly indicate that pressure sensitive switches can also be employed.

Claims 8 and 9 each depend from Claim 7, thus the amendment to Claim 7 obviates the indefiniteness rejection of all of Claims 7-9. Accordingly, the indefiniteness rejection of Claims 7-9 should be withdrawn.

Claims Rejected under 35 U.S.C. § 102

The Examiner has rejected Claim 1 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,951,301 (Younker). The Examiner has also rejected Claims 2-3, 7, 15, 16, 20-25, 26-30, 31, 34-35, 37, 43-45, 47-50, 53-61, 74, and 77-78 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0068606 (Nicholls et al., hereinafter referred to as "Nicholls"), Applicant respectfully disagrees with this rejection for the following reasons.

In the interest of reducing the complexity of the issues for the Examiner to consider in this response, the following discussion focuses on independent Claims 1, 2, 45, 55, 57, and 74. Please note that although the patentability of at least one dependent claim is discussed, the patentability of each remaining dependent claim is not necessarily separately addressed in detail. However, applicant's decision not to discuss the differences between the cited art and each dependent claim should not be considered as an admission that applicant concur with the Examiner's conclusion that these dependent claims are not patentable over the disclosure in the cited references. Similarly, applicant's decision not to discuss differences between the prior art and every claim element, or every comment made by the Examiner, should not be considered as an admission that applicant concur with the Examiner's interpretation and assertions regarding those claims. Indeed, applicant believes that all of the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend.

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Patentability of Independent Claim 1

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that an evaluation circuit is configured to provide the signal when a manipulation of at least a portion *of the simulated physiological structure* causes a conductive path through the evaluation circuit to be opened, wherein the conductive path through evaluation circuit was complete prior to the start of the manipulation. Applicant's Claim 1 has been amended to generally recite a portion of Claim 15 as follows:

> A physiological training and evaluation simulator suitable for training and testing personnel, comprising a simulated physiological structure and an evaluation circuit including a conductive elastomer, wherein a conductive path through the evaluation circuit is complete prior to a manipulation of at least a portion of the simulated physiological structure and said evaluation circuit is configured to provide a signal when the manipulation of said at least the portion of the simulated physiological structure causes the conductive path through the evaluation circuit to be opened.

Support for this amendment is found in the specification as follows:

> Preferably, the electrical evaluation circuit is disposed proximate a location on the simulated physiological structure at which a medical device will be employed in a simulated medical procedure, to evaluate if the person performed the simulated medical procedure properly. For example, the electrical evaluation circuit can be included under the outer layer(s) of the simulated physiological structure as the physiological training and evaluation simulator is constructed. The electrical evaluation circuit can be configured to include a gap, such that sides of the gap formed in the electrical evaluation circuit are electrically coupled to form a complete circuit by a conductive medical device, when the medical device is properly utilized to perform the simulated procedure. Alternatively, the electrical evaluation circuit can be configured to be complete, so that a portion of the electrical evaluation circuit is broken or cut by a medical device to open the circuit, when the medical device is properly utilized to perform the simulated procedure. The electrical evaluation circuit can include a light source to provide a visual indication, and/or an audio source to provide an audible signal to indicate when the medical device is properly utilized to perform the simulated procedure, as described above. (Emphasis added, applicant's specification, page 67, line 22 – page 68, line 7.)

As indicated by the first underlined portion in the citation above, in one embodiment, the evaluation circuit is useful for evaluating whether or not a person performed a simulated medical procedure properly on the simulated physiological structure. As highlighted in the second underlined portion above, in some embodiments a conductive path through the evaluation circuit is initially closed (i.e., complete). However, when simulated physiological structure is manipulated during the

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proper performance of the simulated procedure, the conductive path through the evaluation circuit is broken (or opened). A medical device can be used to break the evaluation circuit (such as a scalpel cutting into a portion of the simulated physiological structure), or a simple manipulation of the simulated physiological structure can break the conductive path through the evaluation circuit (for example, a simulated joint is initially dislocated and the circuit is complete, but when the joint is returned to a correct anatomical position, the circuit is broken).

In contrast, the cited art does not teach or suggest that an evaluation circuit is initially closed prior to manipulation of the simulated physiological structure, and then opened as a result of the manipulation. Instead, the cited art teaches a circuit that is initially open prior to the simulated procedure, and closed as a result of simulated procedure (when the energized tool contacts a portion of the circuit, thereby completing the evaluation circuit).

With respect to Younker, it is important to recognize that while Younker discloses a physiological training and evaluation simulator including a conductive elastomer, the conductive elastomer disclosed by Younker is not equivalent to an evaluation circuit including a conductive elastomer. Younker's physiological training and evaluation simulator includes a conductive elastomer so that the portion of the simulator including the conductive elastomer is electro-cauterizable, for the purpose of simulating electro-cauterization procedures. The conductive elastomer disclosed by Younker is not part of an evaluation circuit configured to provide feedback regarding a simulated medical procedure. Furthermore, a combination of Younker and Nicholls would result in a physiological training and evaluation simulator that includes electro-cauterizable portions, and an evaluation circuit that is configured as being initially open, such that the evaluation circuit is closed during a simulated medical procedure. Clearly, this result is not equivalent to the structure recited in Claim 1 as amended.

It should be noted that Claim 1 is based on an element previously recited in Claim 15, and the Examiner has asserted that Nicholls anticipates Claim 15. Applicant respectfully submits that the subject matter of original Claim 15 and Claim 1 as amended both distinguish over Nicholls, because Nicholls' evaluation circuit responds to a simulated medical procedure causing the evaluation circuit to be closed, not opened. With respect to Claim 15, the Examiner has asserted that removal of the needle in paragraph 14 of Nicholls would result in an opening of the circuit, which provides a signal

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indicating that the needle has been removed (i.e., manipulated). Applicant disagrees with that conclusion. Paragraph 14 is reproduced below:

> The simulation of the nerve preferably includes a plurality of alternating conductive and insulating layers. The sensor means preferably comprises a network of electrical contacts at each conductive layer or element. Electrical contact with each of these independent layers by means of an ***electrically charged needle or implement*** will complete an electrical circuit so that needle location can be evaluated. Measurement of various electrical characteristics (e.g., resistance or capacitance) within the conductive layer can be used to provide additional information (e.g., relative position of contact within the layer or electrical current flow within the layer.) (Emphasis added, Nicholls, paragraph 0014.)

As indicated by the underlined portion (and particularly, by the italicized and bold font portion) above, the circuit is completed when electrical contact is made with each independent layer. Therefore, prior to manipulation of the simulator in Nicholls, the conductive path through the evaluation circuit is open, unlike the recitation of applicant's Claim 1, wherein prior to manipulation of the simulator, the conductive path through the evaluation circuit is complete or closed.

Accordingly, the rejection of independent Claim 1 under 35 U.S.C. § 102(b) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 1.

Patentability of Independent Claim 2

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest an *evaluation circuit being configured to provide a signal relating to a simulated procedure being performed on the simulated physiological structure, without requiring an electrical current to be provided by an instrument placed in contact with the evaluation circuit during the simulated procedure.*

Support for this amendment is provided in the specification as follows:

> FIGURE 10D shows a closely related conductive elastomer-based evaluation circuit 342b, in which a probe 338d is not initially coupled to power source 332. Probe 338d must be conductive. Circuit 342b includes a charged target 339b as well as target 339a. When the probe is properly employed to execute a simulated medical procedure, the probe couples charged target 339b to target 339a, thereby completing the circuit. Circuit 342b has the advantage over circuit 342a in that probe 338d is not required to be coupled directly to the power source, as is required in circuit 342a. This enables probe 338d to be more freely manipulated by the student, and thus enables a more realistic simulation. Circuit 342b is particularly well suited to be used in conjunction with simulated procedures involving needle insertion. Medical needles are readily conductive, thus a specialized probe is not required. Note that circuit 342b

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> is functionally very similar to circuit 330 (FIGURE 10A), the only difference being the inclusion of targets 339a and 339b. As noted above, target 339a can be implemented as a thin sheet, strips, or a grid. Charged target 339b should be at least as large as target 339a, and can be implemented as substantially larger than target 339a. The targets (particularly when implemented as sheets) must be spaced far enough apart so as not to share charges as would opposed plates of a capacitor, as indicator 334 should be triggered only when probe 338d actually physically couples the targets together during the proper execution of a simulated procedure. Again, targets 339a and 339b will normally be hidden from view, such that the student will need to rely on feedback provided by the evaluation circuit to determine if probe 338d actually connected with the target as desired. Note that portions of circuit 342a (as well as portions of the other circuits discussed above) may be implemented with convention conductors and wiring, but targets 339a and 339b are preferably implemented as conductive elastomers, as those portions of the circuit will be incorporated into the medical model, where the presence of conventional circuit elements would not be realistic. (Emphasis added, specification, page 38, line 6 – page 39, line 2.)

Applicant's specification describes not only the embodiment disclosed by Nicholls, where an energized tool completes an evaluation circuit during proper performance of a simulated medical procedure, but other embodiments as well, where an energized tool is not required. These other embodiments include evaluation circuits configured to respond to pressure (as opposed to contact with an energized tool), evaluation circuits configured to respond to temperature (as opposed to contact with an energized tool), evaluation circuits configured to respond to chemical changes (as opposed to contact with an energized tool), evaluation circuits configured to respond to the circuit changing from closed to open (as opposed to contact with an energized tool that drives the circuit), evaluation circuits configured to respond to a conductive path through the circuit changing from open to closed, where the circuit is closed by bridging a gap in the circuit using a conductive tool that is not energized (as opposed to bridging the gap in the circuit using a conductive tool that is energized), and evaluation circuits configured to respond to a conductive path through the circuit changing from open to closed, where the conductive path through circuit is closed by bridging a gap in the circuit, e.g., by moving one portion of the circuit into contact with another portion of the circuit, those portions being part of the simulated physiological structure (as opposed to a moving portion being an energized tool that is not part of the simulated physiological structure).

In contrast, Nicholls ***only*** teaches using an instrument to provide a signal to a circuit when the instrument is coupled to a power source. In paragraph 0014, Nicholls teaches that "electrical contact with

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each of these independent layers by means of an electrically charged needle or implement will complete an electrical circuit so that needle location can be evaluated." And as shown in FIGURE 1, needle 17 is in connected to nerve stimulator device 19, which is unlike the additional embodiments disclosed by applicant that do not require an energized tool to complete or drive the evaluation circuit. None of the cited art teaches or suggests the modifications to Nicholls training simulator that would be required to achieve the exemplary embodiments disclosed by applicant that are recited in the amended claim.

Accordingly, the rejection of independent Claim 2 under 35 U.S.C. § 102(e) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 3-12, 14-41, 43 and 44 are patentable for at least the reasons discussed above in regard to independent Claim 2, and the rejection of dependent Claims 3, 7, 20-25, 26-30, 31, 34-35, 37, and 43-44 under 35 U.S.C. § 102(e) should be withdrawn. Note that Claims 13 and 42 have been canceled without prejudice, and their rejection is now moot.

Patentability of Independent Claim 45

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that any simulated procedure requires causing *conductive portions of the simulated physiological structure to be brought in contact with one another* in order for the circuit to be completed. Independent Claim 45 has been amended and now recites:

> A medical training simulator suitable for medical skills training and evaluation, the medical training model comprising a simulated physiological structure and an evaluation circuit including a conductive elastomer, the evaluation circuit including a first conductive segment and a second conductive segment disposed adjacent to each other, without being electrically coupled to each other, the first conductive segment and the second conductive segment being part of the simulated physiological structure, said evaluation circuit being configured to provide data related to proper execution of a simulated medical procedure being performed using the simulated physiological structure when the first conductive segment and the second conductive segment are placed in physical contact with each other during the simulated medical procedure, thereby completing the evaluation circuit and enabling the evaluation circuit to provide the data related to the proper execution of the simulated medical procedure.

It should be noted that applicant's specification clearly discloses two different embodiments encompassed by Claim 45; a first embodiment where a gap between adjacent portions of the evaluation circuit is closed by deforming the simulated physiological structure until the adjacent portions are in contact (FIGURE 11B); and, a second embodiment where a non conductive portion of the simulated physiological structure is removed, and adjoining portions of the simulated physiological structure are

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sutured together (FIGURE 22C). Significantly, these embodiments are based on manipulations of the simulated physiological structure where both parts of the circuit that are being manipulated are part of the simulated physiological structure. In Nicholls' simulator, one part of the circuit is the simulated physiological structure, but the other part of the circuit is an energized simulated medical device. Claim 45 specifically recites that the relevant portions of the evaluation circuit are part of the simulated physiological structure.

With respect to FIGURE 11B, the specification discloses that the "*gap separating the portions is maintained until a sufficient deforming force or pressure is applied. The force or pressure is either applied with a probe 338d to the elastomeric portion of either of portions 347a and 347b, or can be applied manually by the person being evaluated, using a finger or a hand. In response to the force or pressure applied, the affected elastomeric portion deforms until it contacts the opposing portion, thereby completing the circuit and conducting an electrical current. Indicator 334 registers that the circuit is closed.*" Note that while a tool can be used to apply pressure, the portions of the circuit being placed in electrical contact are elastomeric. Thus, the tool is not touching the circuit, it is simply moving portions of the circuit comprising the simulator into contact with one another, which is fundamentally different than the functional characteristics of Nicholls' device.

With respect to FIGURE 22 the specification discloses:

> FIGURE 22C illustrates a human patient simulator 480b which includes a conductive elastomer-based evaluation circuit that is configured to be completed when a simulated portion of tissue is removed and adjoining tissue is sutured together. Human patient simulator 480a includes simulated intestines 491. At least one portion 493 of intestines 491 includes a blockage that must be removed. Portion 493 is logically coupled to processor 494, and is shown in an enlarged view. Portion 493 is a generally tubular elastomeric structure that includes portions 495 which are conductive, and portion 497 (representing a blockage) that is not conductive. Removal of portion 497, and properly joining portions 495, will complete the conductive elastomeric evaluation circuit and processor 494 will receive a signal. Substantially all of portions 495 can be conductive, or if desired only limited sections of portions 495 can be made conductive. The less of portions 495 that are conductive, the more critical it is that relative alignment between opposed portions 495 be correct when the opposed portions are sutured together. When less than all of portions 495 are conductive, misalignment between the conductive sections of portions 495 will cause the circuit to remain open. Non conductive portion 497 may be configured to be visually distinguishable from portions 495. For example, some blockages are a result of a diseased condition which results in visible changes to tissue. It should be understood that human patient simulator 480b can include other conductive elastomer-based evaluation circuits as well. Further, the removal of a portion of a simulated

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physiological structure to complete a circuit is not limited to simulated intestines. Such a configuration can be applied to simulated veins, simulated arteries, and other physiological structures. (Emphasis added, specification, page 74, lines 3-26.)

As indicated by the underlined portion above, an example of a simulated medical procedure that requires the excision of a non conductive portion and requires the conductive portions to be coupled to complete the circuit is a procedure that simulates a blockage in the intestines wherein removal of portion 497 that represents the blockage is necessary so that portions 495 can be electrically joined together.

Clearly, Claim 45 as amended employs an operational principle that is distinguishable from that employed by Nicholls. The cited art does not teach or suggest the modifications to Nicholls required to achieve an equivalent evaluation circuit. Furthermore, there is no evidence that the modifications required to Nicholls would solve any problem recognized in the art, or that such modifications simply represent matter of design.

The Examiner has asserted that Nicholls teaches that the insertion of the probe into the simulated skin displaces (removes) the insulator as the probe is inserted into the simulated structure a certain distance (gap) to contact the conductive elastomer portion of the evaluation circuit, thus completing the circuit. Applicant respectfully submits that such a technique is not equivalent to what has been claimed. Note that Claim 45 recites that an evaluation circuit configured such that the proper execution of a simulated medical procedure causes *the first conductive segment and the second conductive segment* to be *placed in physical contact with each other during the simulated medical procedure, thereby completing the evaluation circuit.* Claim 45 also requires that those segments be part of the simulated physiological structure (as is the case with FIGURE 22C, and embodiments consistent with FIGURE 11B - the specification clearly disclosing that all or part of the evaluation circuit can be incorporated into the simulated physiological structure). According to Nicholls, the energized probe is part of the circuit, which is not equivalent to the claimed structure. There is no teaching in Nicholls that conductive portions of the *simulated physiological structure* are caused to be joined together in order to complete the circuit.

Accordingly, the rejection of independent Claim 45 under 35 U.S.C. § 102(e) should be withdrawn because the cited art does not teach or suggest all of the claim recitation of Claim 45. Because dependent claims include all of the elements of the independent claim from which the

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dependent claims ultimately depend, dependent Claims 48-54 are patentable for at least the reasons discussed above in regard to independent Claim 45, and the rejection of dependent Claims 48-54 under 35 U.S.C. § 102(e) should be withdrawn (Claims 46 and 47 having been canceled).

Patentability of Independent Claim 55

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that the evaluation circuit is configured as recited in the amended claim. Claim 55 has been amended as follows:

> A medical training simulator suitable for medical skills training and evaluation, the medical training simulator comprising a simulated physiological structure and an evaluation circuit including a conductive elastomer, said conductive elastomer comprising a first elastomeric layer, a second elastomeric layer, and a conductor encapsulated by the first and second elastomeric layers, wherein the evaluation circuit is configured to provide data in response to at least one of the following conditions:
> (a) a specific portion of the simulated physiological structure is manipulated without using an instrument configured to introduce an electrical current into the evaluation circuit;
> (b) pressure is applied to at least a portion of the simulated physiological structure without using an instrument configured to introduce an electrical current into the evaluation circuit;
> (c) at least a portion of the simulated physiological structure is touched without using an instrument configured to introduce an electrical current into the evaluation circuit;
> (d) a manipulation of at least a portion of the simulated physiological structure causes the evaluation circuit to close, without using an instrument configured to introduce an electrical current into the evaluation circuit;
> (e) a manipulation of at least a portion of the simulated physiological structure causes the evaluation circuit to open;
> (f) a sensor coupled to the evaluation circuit detects a change in a non-electrical physical property; and
> (g) an instrument is placed in proximity to at least a portion of the simulated physiological structure, the instrument not being configured to introduce an electrical current into the evaluation circuit.

As discussed above, Nicholls' evaluation circuit requires electrical current to flow from a power supply, through a simulated medical device, and into a conductive elastomer incorporated into a simulated physiological structure. Applicant's specification discloses many embodiments in which the evaluation circuit does not rely on current provided by an energized simulated medical instrument or device. Those embodiments include: FIGURES 11A, 11B, 14B, 11C-11E, and 22A, where a specific portion of the simulated physiological structure is manipulated without using an instrument configured to introduce an electrical current into the evaluation circuit; FIGURES 11A, 11B, and

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14B, where pressure is applied to at least a portion of the simulated physiological structure without using an instrument configured to introduce an electrical current into the evaluation circuit; FIGURES 11A, 11B, and 14B, where at least a portion of the simulated physiological structure is touched without using an instrument configured to introduce an electrical current into the evaluation circuit; FIGURES 11B, 14B, 11C-11E, and 22A, where a manipulation of at least a portion of the simulated physiological structure causes the evaluation circuit to close, without using an instrument configured to introduce an electrical current into the evaluation circuit; FIGURE 10B, where a manipulation of at least a portion of the simulated physiological structure causes the evaluation circuit to open; and FIGURES 11A, 11B, 14B, and 22A, where an instrument is placed in proximity to at least a portion of the simulated physiological structure, the instrument not being configured to introduce an electrical current into the evaluation circuit.

Nicholls simply does not teach or suggest evaluation circuits having configurations equivalent to what applicant claims. Nor is there any evidence that such configuration would have been obvious design variations, or would have solved any recognized problems. Accordingly, the rejection of independent Claim 55 under 35 U.S.C. § 102(e) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claim 56 is patentable for at least the reasons discussed above in regard to independent Claim 55, and the rejection of dependent Claim 56 under 35 U.S.C. § 102(e) should be withdrawn.

Furthermore, Claim 56 has been amended to recite that the evaluation circuit comprises a three dimensional grid. Such a configuration is shown in FIGURE 23. While Nicholls clearly discloses conductive layers disclosed in a three dimensional layered array, not all three dimensional arrays are grids. The configuration shown in FIGURE 23 and recited in Claim 56 is not taught or suggested by Nicholls.

Patentability of Independent Claim 57

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that the evaluation circuit is configured as recited in the amended claim. Claim 57 has been amended as follows:

> A method for making a medical training simulator suitable for medical skills training and evaluation, the method comprising the steps of:

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(a) determining a physiological structure that the medical training simulator is to simulate;
(b) determining a simulated medical procedure that will be performed on a simulated physiological structure corresponding to the physiological structure; and
(c) constructing a medical training simulator including:
(i) a simulated physiological structure corresponding to the physiological structure of step (a); and
(ii) an evaluation circuit comprising a conductive elastomer, the evaluation circuit being configured to provide feedback relating to the simulated medical procedure of step (b), such that the evaluation circuit provides the feedback without the input of an electrical current received from an instrument employed in the simulated medical procedure.

As discussed in detail above, Nicholls' device requires electrical current to be introduced into the evaluation circuit using an energized simulated medical instrument. Applicant's specification discloses many different embodiments where the evaluation circuit configuration functions using different principles of operation. Nicholls does not teach or suggest any other principle of operation, other than completing an evaluation circuit using an energized medical instrument.

Accordingly, the rejection of independent Claim 57 under 35 U.S.C. § 102(e) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 58-61 are patentable for at least the reasons discussed above in regard to independent Claim 57, and the rejection of dependent Claims 58-61 under 35 U.S.C. § 102(e) should be withdrawn.

Patentability of Independent Claim 74

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that the evaluation circuit is configured as recited in the amended claim. Claim 74 as amended reads as follows:

A method for using a medical training simulator for medical skills training and evaluation, comprising the steps of:
(a) providing a medical training simulator comprising a simulated physiological structure a conductive elastomer-based evaluation circuit configured to evaluate a simulated medical procedure; and
(b) using the conductive elastomer-based evaluation circuit to monitor a person's performance of the simulated medical procedure, wherein the evaluation circuit produces an indication of the performance without using an electrical input received from an

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instrument when the instrument contacts the evaluation circuit during the simulated medical procedure.

As discussed in detail above, Nicholls' device requires electrical current to be introduced into the evaluation circuit using an energized simulated medical instrument. Applicant's specification discloses many different embodiments covered by this claims where the evaluation circuit configuration functions using different principles of operation than taught by Nicholls. Nicholls does not teach or suggest any other principle of operation, other than completing an evaluation circuit using an energized medical instrument.

Accordingly, the rejection of independent Claim 74 under 35 U.S.C. § 102(e) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 77-78 are patentable for at least the reasons discussed above in regard to independent Claim 74, and the rejection of dependent Claims 77-78 under 35 U.S.C. § 102(e) should be withdrawn.

Claims Rejected under 35 U.S.C. § 103

The Examiner has rejected Claims 8-9 and 51-52 under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of D'Antonio et al. (U.S. Patent No. 5,589,639, hereinafter referred to as "D'Antonio"). The Examiner has also rejected Claims 30 and 76 under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Boscaro Gatti et al. (U.S. Patent No. 4,459,113, hereinafter referred to as "Gatti"). Claims 32-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Chosack et al. (U.S. Patent No. 6,857,878, hereinafter referred to as "Chosack"). Claims 38-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Strover et al. (U.S. Patent No. 5,967,790, hereinafter referred to as "Strover"). Claim 75 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Pugh (U.S. Patent No. 6,857,878). Claims 79-81 and 85-87 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Beach et al. (U.S. Patent No. 6,857,878, hereinafter referred to as "Beach"). Claims 82-84 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nicholls in view of Beach, and further in view of Younker and Chosack. Applicant respectfully disagrees with these rejections for at least the following reasons.

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Patentability of Independent Claim 79

Significant differences exist between the recited subject matter and the cited art because the cited art does not teach or suggest that the evaluation circuit is configured as recited in the amended claim. Claim 79 has been amended to read as follows:

> A physiological training and evaluation simulator system for training and testing personnel, comprising:
> (a) a simulated physiological structure including a conductive elastomer-based evaluation circuit configured to provide data relating to a simulated procedure being performed on the simulated physiological structure without using an electrical input received from an instrument when the instrument contacts the evaluation circuit during the simulated medical procedure; and
> (b) a controller coupled to the conductive elastomer-based evaluation circuit, the controller being configured to implement a plurality of functions, including:
> (i) storing data obtained from the conductive elastomer-based evaluation circuit, and
> (ii) processing the data obtained from the conductive elastomer-based evaluation circuit to determine a score rating a quality of the simulated procedure.

As discussed in detail above, Nicholls' device requires electrical current to be introduced into the evaluation circuit using an energized simulated medical instrument. Applicant's specification discloses many different embodiments where the evaluation circuit configuration functions using different principles of operation. Nicholls does not teach or suggest any other principle of operation, other than completing an evaluation circuit using an energized medical instrument. The additional references cited by the Examiner with respect to the rejection of Claim 79 do not teach the additional elements introduced into Claim 79 via the current amendment, and thus, the combinations proposed by the Examiner cannot achieve an equivalent to that recited by applicant.

Accordingly, the rejection of independent Claim 79 under 35 U.S.C. § 103(a) should be withdrawn. Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, dependent Claims 80-81 and 85-87 are patentable for at least the reasons discussed above in regard to independent Claim 79, and the rejection of dependent Claims 80-81 and 85-87 under 35 U.S.C. § 102(e) should be withdrawn.

Patentability of Dependent Claims

Because dependent claims include all of the elements of the independent claim from which the dependent claims ultimately depend, the dependent Claims rejected over Nicholls in combination with various cited art, are all patentable for at least the reasons as the independent claims from which the

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dependent claims depend. Accordingly, the rejections of dependent Claims 8, 30, 32-33, 38-41, 51-52, 75, 76 and 82-84 should be withdrawn.

Conclusion

In view of the amendments and the remarks submitted above, it should be apparent that all of the claims now submitted define patentable subject matter that is neither anticipated nor obvious in view of the prior art cited. Therefore, the Examiner is requested to issue the present patent. If there are any questions that might be addressed by a telephone interview, the Examiner is invited to telephone the undersigned attorney, at the number listed below.

Respectfully submitted,

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